

110TH CONGRESS
1ST SESSION

S. 1551

To amend the Public Health Service Act with respect to making progress toward the goal of eliminating tuberculosis, and for other purposes.

IN THE SENATE OF THE UNITED STATES

JUNE 5, 2007

Mr. BROWN (for himself, Mrs. HUTCHISON, Mr. KENNEDY, Mrs. CLINTON, and Mrs. MURRAY) introduced the following bill; which was read twice and referred to the Committee on Health, Education, Labor, and Pensions

A BILL

To amend the Public Health Service Act with respect to making progress toward the goal of eliminating tuberculosis, and for other purposes.

1 *Be it enacted by the Senate and House of Representa-*
2 *tives of the United States of America in Congress assembled,*

3 **SECTION 1. SHORT TITLE; TABLE OF CONTENTS.**

4 (a) SHORT TITLE.—This Act may be cited as the
5 “Comprehensive Tuberculosis Elimination Act of 2007”.

6 (b) TABLE OF CONTENTS.—The table of contents for
7 this Act is as follows:

Sec. 1. Short title; table of contents.

Sec. 2. Findings.

TITLE I—CENTERS FOR DISEASE CONTROL AND PREVENTION

Subtitle A—National Program for Elimination of Tuberculosis

Sec. 101. National program.

Subtitle B—Interagency Collaboration

Sec. 111. Advisory council for elimination of tuberculosis.

Subtitle C—New Tools for Tuberculosis Elimination

Sec. 121. New tools.

Subtitle D—Authorizations of Appropriations

Sec. 131. Authorizations of appropriations.

TITLE II—NATIONAL INSTITUTES OF HEALTH

Sec. 201. Research and development concerning tuberculosis.

Sec. 202. Activities of National institute of Allergy and Infectious Diseases.

Sec. 203. John E. Fogarty International Center for Advanced Study in the Health Sciences.

Sec. 204. Loan repayment programs regarding research on tuberculosis.

Sec. 205. Authorization of appropriations.

1 SEC. 2. FINDINGS.

2 The Congress finds as follows:

3 (1) Each year approximately 9,000,000 people
 4 become ill with active tuberculosis (referred to in
 5 this section as “TB”), and it is estimated that
 6 1,600,000 of those people die, a result of critical
 7 underinvestment in quality TB control and the re-
 8 search and development of new TB drugs,
 9 diagnostics and a vaccine, as well as the comorbid
 10 relationship between TB and HIV/AIDS. Such levels
 11 of morbidity and mortality are complicated by the
 12 disease having the ability to develop resistance to
 13 treatments and to travel easily across borders.

1 (2) In 2006, there were 13,767 cases of active
2 TB reported in the United States. The average an-
3 nual decline in the national TB rate slowed from 7.3
4 percent per year in the period of 1993 to 2000 to
5 3.8 percent per year in the period of 2000 to 2006.

6 (3) In addition to those with active TB, an esti-
7 mated 10,000,000 to 15,000,000 people in the
8 United States have latent TB infection.

9 (4) The increasing occurrence of multidrug re-
10 sistant (“MDR”) TB, including extensively drug re-
11 sistant (“XDR”) TB—which is resistant to at least
12 almost all drugs used to treat TB, including the two
13 recommended first-line drugs and the recommended
14 second-line medications, raises concerns of a future
15 epidemic of virtually untreatable TB.

16 (5) To prevent the spread of extensively drug
17 resistant TB, the immediate strengthening of TB
18 control systems must be a priority. This includes im-
19 proved case detection, strengthened laboratory ca-
20 pacity, rapid implementation of infection control
21 measures, enhanced treatment programs, and imme-
22 diate support to existing public sector infrastructure.

23 (6) The Centers for Disease Control and Pre-
24 vention is increasingly relied upon globally for its ex-
25 pertise and technical assistance in global tuber-

culosis preparedness and outbreak response capacity to identify and investigate outbreaks of multidrug resistant and extensively drug resistant TB.

(7) New tools are needed to more effectively prevent, diagnose, and treat TB. The standard method of diagnosing TB is over 100 years old, and fails to adequately detect TB, especially in children and those co-infected with HIV/AIDS. The newest class of anti-TB drug is over 40 years old, while rates of multidrug resistant TB are rising globally. The existing vaccine confers no protection to adolescents and adults, protecting only against severe forms of TB in infants and young children.

TITLE I—CENTERS FOR DISEASE CONTROL AND PREVENTION

Subtitle A—National Program for Elimination of Tuberculosis

SEC. 101. NATIONAL PROGRAM.

Section 317E of the Public Health Service Act (42 U.S.C. 247b–6) is amended—

(1) by striking the heading for the section and inserting the following: “NATIONAL PROGRAM FOR ELIMINATION OF TUBERCULOSIS”; and

(2) by amending subsection (b) to read as follows:

1 “(b) RESEARCH AND DEVELOPMENT; DEMONSTRA-
2 TION PROJECTS; EDUCATION AND TRAINING.—With re-
3 spect to the prevention, treatment, control, and elimi-
4 nation of tuberculosis, the Secretary may, directly or
5 through grants to public or nonprofit private entities,
6 carry out the following:

7 “(1) Research, with priority given to research
8 and development concerning—

9 “(A) clinical trials to evaluate the safety
10 and effectiveness of new drugs, diagnostics, and
11 vaccines for latent tuberculosis infection and ac-
12 tive tuberculosis, including drug-resistant tuber-
13 culosis, that are suitable for use by patients
14 with HIV/AIDS;

15 “(B) epidemiological studies of populations
16 at risk for tuberculosis; and

17 “(C) field studies to evaluate the effective-
18 ness of new drugs, diagnostics, and vaccines, to
19 assess the incidence and prevalence of
20 multidrug resistant and extensively drug resist-
21 ant strains of tuberculosis.

22 “(2) Demonstration projects for—

23 “(A) the development of regional capabili-
24 ties to prevent, control and eliminate tuber-

1 culosis and prevent multidrug resistant and ex-
2 tensively drug resistant strains of tuberculosis;

3 “(B) the intensification of efforts—

4 “(i) to prevent, detect, and treat tu-
5 berculosis among African Americans, His-
6 panic Americans, Asian Americans, and
7 other United States-born populations with
8 documented health disparities; and

9 “(ii) to reduce or eliminate racial dis-
10 parities in the incidence of tuberculosis in
11 these populations;

12 “(C) the intensification of efforts to con-
13 trol tuberculosis along the United States-Mexico
14 border and among United States-Mexico bina-
15 tional populations;

16 “(D) the intensification of efforts to pre-
17 vent, detect, and treat tuberculosis among for-
18 eign-born persons who are in the United States;

19 “(E) providing guidance to Immigration
20 and Customs Enforcement in developing risk-
21 based screening procedures based on current
22 epidemiological data;

23 “(F) the intensification of efforts to in-
24 crease targeted testing and treatment of latent

1 tuberculosis infection and drug-resistant tuber-
2 culosis; and

3 “(G) the intensification of efforts to pre-
4 vent, detect, and treat tuberculosis among other
5 high risk populations and settings, including
6 among children and adolescents, homeless per-
7 sons, detainees and prisoners, HIV-infected per-
8 sons, and within health care settings.

9 “(3) A public information and education pro-
10 gram to include components that raise awareness re-
11 garding tuberculosis among the general population
12 as well as those that target populations documented
13 as having high risk for tuberculosis.

14 “(4) Education, training and clinical skills im-
15 provement activities for health professionals, includ-
16 ing allied health personnel and emergency response
17 employees.

18 “(5) Provide support for the Tuberculosis
19 Trials Consortium, the Tuberculosis Epidemiologic
20 Studies Consortium, the National Laboratory Train-
21 ing Network, and Regional Training and Medical
22 Consultation Centers to carry out activities under
23 paragraphs (1) through (4).

24 “(6) Collaboration with international organiza-
25 tions and foreign countries in intensifying efforts to

1 prevent, treat, control, and eliminate tuberculosis,
 2 including efforts that address risks associated with
 3 international travel.

4 “(7) Develop, enhance, and expand information
 5 technologies that support tuberculosis control, in-
 6 cluding surveillance and database management sys-
 7 tems with cross-jurisdictional capabilities.”.

8 **Subtitle B—Interagency** 9 **Collaboration**

10 **SEC. 111. ADVISORY COUNCIL FOR ELIMINATION OF TU-** 11 **BERCULOSIS.**

12 (a) IN GENERAL.—Section 317E(f) of the Public
 13 Health Service Act (42 U.S.C. 247b–6(f)) is amended—

14 (1) by redesignating paragraph (5) as para-
 15 graph (6); and

16 (2) by striking paragraphs (2) through (4), and
 17 inserting the following:

18 “(2) DUTIES.—The Council shall provide advice
 19 and recommendations regarding the elimination of
 20 tuberculosis to the Secretary, the Assistant Sec-
 21 retary for Health, and the Director of the Centers
 22 for Disease Control and Prevention. In addition, the
 23 Council shall, with respect to eliminating such dis-
 24 ease, provide to the Secretary and other appropriate
 25 Federal officials advice on—

1 “(A) coordinating the activities of the Pub-
2 lic Health Service and other Federal agencies
3 that relate to the disease, including activities
4 under subsection (b);

5 “(B) responding rapidly and effectively to
6 cases of extensively drug resistant strains of tu-
7 berculosis; and

8 “(C) efficiently utilizing the Federal re-
9 sources involved.

10 “(3) COMPREHENSIVE PLAN.—

11 “(A) IN GENERAL.—In carrying out para-
12 graph (2), the Council shall make recommenda-
13 tions on the development, revision, and imple-
14 mentation of a comprehensive plan to eliminate
15 tuberculosis in the United States.

16 “(B) CONSULTATION.—In carrying out
17 subparagraph (A), the Council shall consult
18 with public and private entities, including—

19 “(i) individuals who are scientists,
20 physicians, laboratorians, and other health
21 professionals, who are not officers or em-
22 ployees of the Federal Government and
23 who represent the disciplines relevant to
24 tuberculosis elimination;

1 “(ii) members of public-private part-
2 nerships established to address the elimi-
3 nation of tuberculosis;

4 “(iii) members of national and inter-
5 national nongovernmental organizations es-
6 tablished to address tuberculosis elimi-
7 nation; and

8 “(iv) members from the general public
9 who are knowledgeable with respect to tu-
10 berculosis elimination including individuals
11 who have or have had tuberculosis.

12 “(C) CERTAIN COMPONENTS OF PLAN.—In
13 carrying out subparagraph (A), the Council
14 shall—

15 “(i) consider the recommendations of
16 the Institute of Medicine regarding the
17 elimination of tuberculosis;

18 “(ii) consider recommendations for
19 the involvement of the United States in
20 continuing global and cross-border tuber-
21 culosis control activities in countries where
22 a high incidence of tuberculosis directly af-
23 fects the United States such as Mexico;
24 and

1 “(iii) review the extent to which
2 progress has been made toward eliminating
3 tuberculosis.

4 “(4) ANNUAL REPORT.—The Council shall an-
5 nually submit to Congress and the Secretary a re-
6 port on the activities carried under this section,
7 other than subsection (g). Each such report shall in-
8 clude the opinion of the Council on the extent to
9 which its recommendations regarding the elimination
10 of tuberculosis have been implemented, including
11 with respect to—

12 “(A) activities under subsection (b); and

13 “(B) the national plan referred to in para-
14 graph (3).

15 “(5) COMPOSITION.—The Council shall be com-
16 posed of—

17 “(A) representatives from the Centers for
18 Disease Control and Prevention, the National
19 Institutes of Health, the United States Agency
20 for International Development, the Agency for
21 Healthcare Research and Quality, the Health
22 Resources and Services Administration, the
23 United States-Mexico Border Health Commis-
24 sion, and other Federal departments and agen-

1 cies that carry out significant activities related
2 to tuberculosis;

3 “(B) State and local tuberculosis control
4 and public health officials;

5 “(C) individuals who are scientists, physi-
6 cians, laboratorians, and other health profes-
7 sionals who represent disciplines relevant to tu-
8 berculosis elimination;

9 “(D) members of national and inter-
10 national nongovernmental organizations estab-
11 lished to address the elimination of tuberculosis;
12 and

13 “(E) members from the general public who
14 are knowledgeable with respect to the elimi-
15 nation of tuberculosis, including individuals who
16 have or have had tuberculosis.”.

17 (b) RULE OF CONSTRUCTION REGARDING CURRENT
18 MEMBERSHIP.—With respect to the advisory council
19 under section 317E(f) of the Public Health Service Act,
20 the amendments made by subsection (a) may not be con-
21 strued as terminating the membership on such council of
22 any individual serving as such a member as of the day
23 before the date of the enactment of this Act.

**Subtitle C—New Tools for
Tuberculosis Elimination**

SEC. 121. NEW TOOLS.

Section 317E of the Public Health Service Act (42 U.S.C. 247b–6) is amended—

(1) by redesignating subsection (g) as subsection (h); and

(2) by inserting after subsection (f) the following subsection:

“(g) NEW TOOLS FOR ELIMINATION OF TUBERCULOSIS.—

“(1) RESEARCH AND DEVELOPMENT ON DRUGS, DIAGNOSTICS, VACCINES, AND PUBLIC HEALTH INTERVENTIONS.—The Secretary, acting through the Director of the Centers for Disease Control and Prevention, shall expand, intensify, and coordinate research and development and related activities of such Centers to develop new tools for the elimination of tuberculosis, including drugs, diagnostics, vaccines, and public health interventions, such as directly observed therapy and non-pharmaceutical intervention.

“(2) FEDERAL TUBERCULOSIS TASK FORCE.—

“(A) DUTIES.—The Federal Tuberculosis Task Force (established in December 2001 as

part of the Centers for Disease Control and Prevention) (in this subsection referred to as the ‘Task Force’) shall provide to the Secretary and other appropriate Federal officials advice on the implementation of paragraph (1), including advice regarding the efficient utilization of the Federal resources involved.

“(B) COMPREHENSIVE PLAN FOR NEW TOOLS DEVELOPMENT.—In carrying out paragraph (1), the Task Force shall make recommendations on the development of a comprehensive plan for the creation of new tools for the elimination of tuberculosis, including drugs, diagnostics, and vaccines.

“(C) CONSULTATION.—In developing the comprehensive plan under paragraph (1), the Task Force shall consult with—

“(i) scientists, physicians, laboratorians, and other health professionals and who represent the specialties and disciplines relevant to the research under consideration;

“(ii) members from public-private partnerships or foundations (or both) en-

1 gaged in research relevant to research
2 under consideration;

3 “(iii) members of national and inter-
4 national nongovernmental organizations es-
5 tablished to address tuberculosis elimi-
6 nation;

7 “(iv) members from the general public
8 who are knowledgeable with respect to tu-
9 berculosis, including individuals who have
10 or have had tuberculosis; and

11 “(v) scientists, physicians,
12 laboratorians, and other health profes-
13 sionals who reside in a foreign country
14 with a substantial incidence or prevalence
15 of tuberculosis, and who represent the spe-
16 cialties and disciplines relevant to the re-
17 search under consideration.

18 “(3) GRANTS AND CONTRACTS.—The Secretary
19 shall carry out paragraph (1) directly and through
20 awards of grants, cooperative agreements, and con-
21 tracts to public and private entities, including—

22 “(A) public-private partnerships;

23 “(B) academic institutions, including insti-
24 tutions of higher education;

25 “(C) research institutions; and

1 “(D) the Tuberculosis Trials Consortium
 2 and the Tuberculosis Epidemiologic Studies
 3 Consortium.”.

4 **Subtitle D—Authorizations of** 5 **Appropriations**

6 **SEC. 131. AUTHORIZATIONS OF APPROPRIATIONS.**

7 Section 317E of the Public Health Service Act, as
 8 amended by section 121(1) of this Act, is amended by
 9 striking subsection (h) and inserting the following:

10 “(h) AUTHORIZATION OF APPROPRIATIONS.—

11 “(1) GENERAL PROGRAM.—

12 “(A) IN GENERAL.—For the purpose of
 13 carrying out this section, other than subsections
 14 (b) and (g), there are authorized to be appro-
 15 priated \$300,000,000 for fiscal year 2008, and
 16 such sums as may be necessary for each of the
 17 fiscal years 2009 through 2012.

18 “(B) RESERVATION FOR EMERGENCY
 19 GRANTS.—Of the amounts appropriated under
 20 subparagraph (A) for a fiscal year, the Sec-
 21 retary may reserve not more than 25 percent
 22 for emergency grants under subsection (a) for
 23 any State, political subdivision of a States, or
 24 other public entity in which there is, relative to
 25 other areas, a substantial number of cases of

tuberculosis, multidrug resistant tuberculosis, or extensively drug resistant tuberculosis or a substantial rate of increase in such cases.

“(C) RESEARCH, DEMONSTRATION PROJECTS, EDUCATION, AND TRAINING.—For the purpose of carrying out subsection (b), there are authorized to be appropriated such sums as may be necessary for each of fiscal years 2008 through 2012.

“(D) PRIORITY.—In allocating amounts appropriated under subparagraph (A) and not reserved under subparagraph (B), the Secretary shall give priority to allocating such amounts for grants under subsection (a).

“(E) ALLOCATION OF FUNDS.—

“(i) REQUIREMENT OF FORMULA.—Of the amounts appropriated under subparagraph (A), not reserved under subparagraph (B), and allocated by the Secretary for grants under subsection (a), the Secretary shall distribute such amounts to grantees under subsection (a) on the basis of a formula.

“(ii) RELEVANT FACTORS.—The formula developed by the Secretary under

1 clause (i) shall take into account the level
2 of tuberculosis morbidity in the respective
3 geographic area and may consider other
4 factors relevant to tuberculosis in such
5 area.

6 “(iii) NO CHANGE TO FORMULA RE-
7 QUIRED.—This subparagraph does not re-
8 quire the Secretary to modify the formula
9 that was used by the Secretary to dis-
10 tribute funds to grantees under subsection
11 (a) for fiscal year 2007.

12 “(2) NEW TOOLS.—

13 “(A) IN GENERAL.—For the purpose of
14 carrying out subsection (g), there are author-
15 ized to be appropriated \$100,000,000 for fiscal
16 year 2008, and such sums as may be necessary
17 for each of the fiscal years 2009 through 2012.

18 “(B) LIMITATION.—The authorization of
19 appropriations established in subparagraph (A)
20 for a fiscal year is effective only if the amount
21 appropriated under paragraph (1) for such year
22 equals or exceeds the amount appropriated to
23 carry out this section for fiscal year 2007.”.

1 **TITLE II—NATIONAL INSTITUTES**
2 **OF HEALTH**

3 **SEC. 201. RESEARCH AND DEVELOPMENT CONCERNING TU-**
4 **BERCULOSIS.**

5 (a) IN GENERAL.—Subpart 2 of part C of title IV
6 of the Public Health Service Act (42 U.S.C. 285b et seq.)
7 is amended by inserting after section 424B the following
8 section:

9 **“SEC. 424C. TUBERCULOSIS.**

10 “(a) IN GENERAL.—The Director of the National In-
11 stitutes of Health shall expand, intensify, and coordinate
12 research and development and related activities of the In-
13 stitute with respect to tuberculosis, including activities to-
14 ward the goal of eliminating such disease.

15 “(b) CERTAIN ACTIVITIES.—Activities under sub-
16 section (a) shall include—

17 “(1) enhancing basic and clinical research on
18 tuberculosis, including drug resistant tuberculosis;
19 and

20 “(2) expanding research on the relationship be-
21 tween such disease and the human immunodeficiency
22 virus.”.

23 (b) RESEARCH EDUCATION.—Part A of title IV of
24 the Public Health Service Act (42 U.S.C. 281 et seq.) is
25 amended by adding at the end the following:

1 **“SEC. 404I. TUBERCULOSIS ACADEMIC AWARDS.**

2 “(a) TUBERCULOSIS ACADEMIC AWARDS.—The Di-
 3 rector of the National Institutes of Health may provide
 4 awards to faculty of schools of medicine, osteopathic medi-
 5 cine, nursing, public health, or related fields to assist such
 6 faculty in developing high quality curricula in such schools
 7 designed to significantly increase the opportunities for in-
 8 terested individuals, including students of the school and
 9 practicing physicians and nurses, to learn the principles
 10 and practices of preventing, managing, and controlling tu-
 11 berculosis.

12 “(b) TUBERCULOSIS/PULMONARY INFECTION
 13 AWARDS.—The Director of the National Institutes of
 14 Health may provide awards to support the career develop-
 15 ment of clinically trained professionals who are committed
 16 to research regarding pulmonary infections and tuber-
 17 culosis by providing for supervised study and research.”.

18 **SEC. 202. ACTIVITIES OF NATIONAL INSTITUTE OF AL-**
 19 **LERGY AND INFECTIOUS DISEASES.**

20 Section 447A of the Public Health Service Act (42
 21 U.S.C. 285f–2) is amended—

- 22 (1) by striking “In carrying out section 446”
 23 and inserting “(a) In carrying out section 446”; and
 24 (2) by inserting at the end the following:

25 “(b) Activities under subsection (a) shall include ac-
 26 tivities to develop a tuberculosis vaccine. Such activities

1 shall be carried out in accordance with the blueprint for
 2 tuberculosis vaccine development described in the report
 3 prepared pursuant to the workshop convened in March
 4 1998 by the Advisory Council for Elimination of Tuber-
 5 culosis, the Director of the National Vaccine Program,
 6 and the Director of the Institute.”.

7 **SEC. 203. JOHN E. FOGARTY INTERNATIONAL CENTER FOR**
 8 **ADVANCED STUDY IN THE HEALTH**
 9 **SCIENCES.**

10 Section 482 of the Public Health Service Act (42
 11 U.S.C. 287b) is amended—

12 (1) by inserting “(a) IN GENERAL.—” before
 13 “The general purpose”;

14 (2) in subsection (a) (as so designated), by in-
 15 serting after “Health Sciences” the following: “(in
 16 this subpart referred to as the ‘Center’)”; and

17 (3) by adding at the end the following sub-
 18 section:

19 “(b) TUBERCULOSIS.—

20 “(1) IN GENERAL.—In carrying out subsection
 21 (a) with respect to tuberculosis, the Center shall ex-
 22 pand, intensify, and coordinate international activi-
 23 ties of the Center for research and training.

24 “(2) INTERNATIONAL TRAINING PROGRAM.—In
 25 carrying out paragraph (1), the Center shall carry

1 out an international training program regarding tu-
 2 berculosis. Such program shall be modeled after the
 3 international training program carried out by the
 4 Center with respect to the human immunodeficiency
 5 virus.”.

6 **SEC. 204. LOAN REPAYMENT PROGRAMS REGARDING RE-**
 7 **SEARCH ON TUBERCULOSIS.**

8 Part G of title IV of the Public Health Service Act
 9 (42 U.S.C. 288 et seq.) is amended—

10 (1) by redesignating the second section 487F as
 11 section 487G; and

12 (2) by inserting after section 487G (as so re-
 13 designated) the following section:

14 “LOAN REPAYMENTS REGARDING RESEARCH ON
 15 TUBERCULOSIS

16 “SEC. 487H. In carrying out sections 487C, 487E,
 17 and 487F, the Secretary shall seek to ensure that, for fis-
 18 cal year 2008 and subsequent fiscal years, a portion of
 19 amounts appropriated to carry out such sections is re-
 20 served for the purpose of entering into contracts under
 21 which (in accordance with the section involved) individuals
 22 will conduct research on tuberculosis. The Secretary shall
 23 have sole discretion for the administration of activities
 24 under this section.”.

1 **SEC. 205. AUTHORIZATION OF APPROPRIATIONS.**

2 For the purpose of carrying out this title and the
3 amendments made by this title, there are authorized to
4 be appropriated such sums as may be necessary. Such au-
5 thorization of appropriations shall be in addition to the
6 authorization of appropriations established by section
7 402A(a) of the Public Health Service Act and any other
8 authorization of appropriations available for such purpose.

○